EXHIBIT C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: *Wave 6 Cases*	

EXPERT REPORT OF LAWRENCE LIND, M.D.

UNITED STATES DISTRICT COURT
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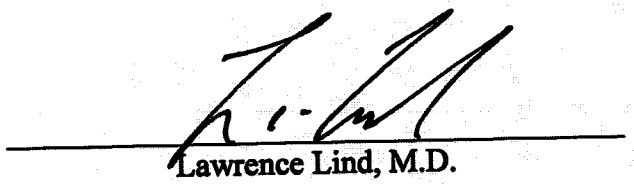
DEFENSE EXPERT GENERAL REPORT
of Lawrence Lind, M.D.:

Prolift and Gynemesh PS

Prepared by:



Lawrence Lind, M.D.

August 13, 2017

I. Background, Qualifications and Experience

I am chief of the Division of Urogynecology and Pelvic Reconstructive Surgery at North Shore University Hospital and Long Island Jewish Medical Center and Medical Director of the Sharon Joyce Schlanger Center for Women's Care. I am a member of the Quality Assurance Committee of North Shore University Hospital and also Associate Professor in Obstetrics and Gynecology at Northwell Health—Hofstra University School of Medicine. I am also on the review board of the scientific journals Obstetrics & Gynecology and International Urogynecology.

I am a member of the American Urogynecologic Society, a Fellow of the American College of Obstetrics & Gynecology and a Fellow of the American College of Surgeons. I am Board certified in Obstetrics and Gynecology with subspecialty Board certification in Female Pelvic Medicine and Reconstructive Surgery. I attended medical school and residency in Obstetrics and Gynecology at Cornell University Medical College, and I completed subspecialty training in Urogynecology and Pelvic Reconstructive Surgery at UCLA Medical Center.

I have authored or co-authored numerous articles in the peer-reviewed scientific literature and book chapters in the field of urogynecology. I have presented abstracts and posters at numerous meetings of professional medical societies, including AUGS, SGS and ACOG. I have taught professional education for Ethicon and Caldera and served on the speaker's bureau of Astella and other pharmaceutical companies.

I am experienced in both native-tissue and mesh-based repairs of pelvic organ prolapse. I was an early adopter of Prolift, having already been a user of Gynemesh PS in transvaginal applications as well as abdominal surgery applications at the time that Prolift was launched. I implanted approximately 100 Prolifts. I have been referred Prolift, Gynemesh PS, and other mesh complication cases by other surgeons in the New York metropolitan area. I have trained 200 residents and 9 fellows on surgical repairs of pelvic organ prolapse, including native-tissue and mesh-augmented repairs.

My *curriculum vitae* is attached.

II. Materials reviewed

I hold the opinions set forth in this report to a reasonable degree of medical and scientific certainty and probability. My opinions and conclusions are based on the practice of evidence-based medicine. I base my opinions on my clinical experience as a practicing urogynecologist; the peer-reviewed scientific literature, with special emphasis on randomized controlled trials, systematic reviews and meta-analyses, which provide the highest levels of scientific evidence; the position statements and practice bulletins published by major urogynecologic and gynecologic and urologic medical societies; my analysis of the Ethicon Instructions for Use and professional education content for implanters of Prolift, including the Surgeon's Resource Monograph, and Ethicon's patient brochures; my participation in professional medical society conferences and events; discussions with my peers; and my education and training. My opinions are also based on my review of deposition testimony and exhibits, expert reports and materials those reports cite to, and materials published by the FDA. A complete list of the materials I have reviewed is attached to this report and will be supplemented as I review additional materials.

III. Fees and Testimonial History

My fees for serving as an expert in this matter are $500 per hour for report writing, review and consultation. For deposition or court testimony, my fee is $7,500/4,500 for a full day or half day, respectively. As of the writing of this report, I have not yet provided expert testimony in the Ethicon pelvic mesh litigation.

IV. Opinions

Pelvic Organ Prolapse

Pelvic organ prolapse is the descent of one or more of the pelvic organs (uterus, vagina, bladder or bowel). Apical prolapse occurs when the upper vagina, i.e., the uterus or vaginal vault, descends; anterior wall prolapse (cystocele) occurs when the bladder descends; and prolapse of the posterior vaginal wall (an enterocele or rectocele) occurs when the small bowel or rectum, respectively, descends. A woman can present with prolapse of one or more vaginal compartments. Pelvic organ prolapse is common and is seen on examination in approximately 50% of parous women. Cystocele is the most common type of pelvic organ prolapse. (Maher, et al, Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse (Review), Cochrane Database of Systematic Reviews 2016, Issue 2, Art. No.: CD012079, DOI:10.1002/14651858; Hendrix, et al, Pelvic organ prolapse in the Women's Health Initiative: Gravity and gravidity, Am J Obstet Gynecol 2002, 186(6):1160-6.)

The etiology of pelvic organ prolapse is complex and multi-factorial. Risk factors include pregnancy, childbirth, congenital or acquired connective tissue abnormalities, denervation or weakness of the pelvic floor, ageing, hysterectomy, menopause and factors associated with chronically increased intra-abdominal pressure such as chronic constipation, obesity, frequent coughing or heavy lifting. (Bump, et al, Epidemiology and Natural History of Pelvic Floor Dysfunction, Obstet Gynecol Clinics N Am 1998 Dec, 25(4):723-747.)

Pelvic organ prolapse is quantified using the POP-Q scoring system or the Baden-Walker system. The Baden-Walker system, of "stages" of prolapse, is still commonly used, but is less precise than POP-Q. POP-Q was described in a 1996 paper published by the International Continence Society and allows effective communication between clinicians, reproducible evaluation of surgical outcomes, meaningful comparison of published series and comparison of different populations. (Reid, Assessment of pelvic organ prolapse: a practical guide to the pelvic organ prolapse quantification, Obstet Gynaecol Reprod Med 2014, 24(6):170-6.)

Symptomatic pelvic organ prolapse is bothersome and can significantly affect quality of life, as is reported in the medical literature and I have seen in my own patients. The condition can affect patients psychologically and socially as well as physically. Patients can experience pelvic heaviness, a bulge or lump in the vagina, a dragging sensation in the vagina, backache, bladder and/or bowel dysfunction (e.g., difficulty voiding or defecating, the need to digitally aid voiding or defecation, or overactive bladder or irritable bowel symptoms), and sexual dysfunction. (Jelovsek, Barber, Women seeking treatment for advanced pelvic organ prolapse have decreased body image and quality of life, Am J Obstet Gynecol 1006 May, 194(5):1455-61; Maher 2016.)

Non-Surgical Treatment Options

Conservative options for managing pelvic organ prolapse include expectant management and use of a pessary. Physicians offer pessaries to women who desire nonsurgical management, future pregnancy, who have early-stage prolapse or are too frail for surgery. Pessaries come in many shapes and sizes and are generally made of silicone. Two to three fittings are typically necessary to find the appropriate device. Pessaries have been demonstrated to improve patient quality of life, but they must be regularly removed, either by the patient or health care provider, for cleaning, and some pessaries must be removed for sexual intercourse. It has been reported in the literature that about half of women discontinue pessary use within three years. Common side effects include vaginal discharge and odor. Serious potential complications include fistula, erosion and impaction. (Jones, Harmanli, Pessary use in pelvic organ prolapse and urinary incontinence, Rev Obstet Gynecol 2010, 3(1):3-9; Dumoulin, et al, Conservative management for female urinary incontinence and pelvic organ prolapse review 2013: Summary of the 5th international consultation on incontinence, Neurourol Urodyn 2016, 35:15-20; Coelho, et al, Female pelvic organ prolapse using pessaries: systematic review, Int Urogynecol J 2016 Dec, 27(12):1797-1803.)

Native Tissue Surgical Repairs and the Problem of Recurrence

Native tissue surgeries to treat pelvic organ prolapse, also called traditional repairs, include anterior colporrhaphy and paravaginal repair to treat cystocele; posterior colporrhaphy and perineorrhaphy to treat rectocele; and uterosacral ligament suspension and sacrospinous ligament fixation to treat vault prolapse. Anterior colporrhaphy was first performed in 1866. (Lensen, et al, Surgical treatment of pelvic organ prolapse: a historical review with emphasis on the anterior compartment, Int Urogynecol J 2013, 24(10):1593-1602.) Colpocleisis is another suture-based repair, although it is an obliterative repair that involves closure of the vagina. Cure rates have been reported as high as 100%, with high rates of satisfaction, but the procedure precludes coital function and for that and other reasons may not be considered desirable. (Brubaker, et al,

Surgery for pelvic organ prolapse, Female Pelvic Med Reconstr Surg 2010 Jan, 16(1):9-19; Takase-Sanchez et al, Obliterative surgery for the treatment of pelvic organ prolapse: a patient survey on reasons for surgery selection and postoperative decision regret and satisfaction, Female Pelvic Med Reconstr Surg 2015, 21:325-331.)

The problem of high failure or recurrence rates with native tissue repairs for prolapse is commonly known to experienced pelvic surgeons. While approximately 11% of all women will undergo surgery to treat pelvic organ prolapse during their lifetime, approximately 30% of patients who undergo a native tissue surgical repair (other than colpocleisis) will require reoperation for re-prolapse. Success rates for native tissue surgical repairs decline over time. The failure rate of native tissue surgical repairs is widely reported to be about 40% and has been reported as high as 70%. Repair of one compartment may predispose patients to prolapse in another compartment. (Olsen, et al, Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence, Obstet Gynecol 1997 Apr, 89(4):501-6; Sung, et al, Graft use in transvaginal pelvic organ prolapse: A systematic review, Obstet Gynecol 2008 Nov, 112(5):1131-42; Jia, et al, Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systematic review and meta-analysis, Br J Obstet Gynaecol 2008, 115(11):1350-61; Nieminen, et al, Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up, Am J Obstet Gynecol 2010 Sept, 235.e1-8; Mettu, et al, Evidence-based outcomes for mesh-based surgery for pelvic organ prolapse, Curr Opin Urol 2014, 24:370-4; Maher 2016; Weber et al, Anterior colporrhaphy: a randomized trial of three surgical techniques, Am J Obstet Gynecol 2001, 185:1299-1306; Paraiso et al, Pelvic support defects and visceral and sexual function in women treated with sacrospinous ligament suspension and pelvic reconstruction, Am J Obstet Gynecol 1996, 175:1423-32; Shull et al, Preoperative and postoperative analysis of site-specific pelvic support defects in 81 women treated with sacrospinous ligament suspension and pelvic reconstruction, Am J Obstet Gynecol 1992, 166:1764-71.)

Native tissue repairs have the disadvantage of using a patient's already weakened or damaged tissue. While cystocele is the most common type of pelvic organ prolapse (constituting 80% of surgical prolapse repairs), traditional anterior repair of cystocele also has a high rate of failure. Failure rates have been widely reported to be 40%, or even more. (Maher 2016; Jia 2008; Withagen 2011; Olsen 1997.) Native tissue posterior repairs have been reported to result in failure rates of 12 to 20%. (Karram et al, Surgery for posterior vaginal wall prolapse, Int Urogynecol J 2013, 24:1835-41; Morgan et al, Heterogeneity in anatomic outcome of sacrospinous ligament fixation for prolapse: a systematic review, Obstet Gynecol 2007 Jun, 109(6):1424-33; Withagen 2011.) Siff and Barber reported that 18% of women will have bothersome vaginal bulge symptoms and 15% will have anterior or posterior prolapse beyond the hymen after USLS or SSLF. (Siff, Barber, Native tissue prolapse repairs: Comparative effectiveness trials, Obstet Gynecol Clin N Am 2016, 43:69-81.) Vault support is important to prolapse repair. Simulated restoration of apical vaginal support appears to correct anterior and posterior vaginal prolapse in 55% and 30% of cases, respectively. (Lowder et al, The role of apical vaginal support in the appearance of anterior and posterior vaginal prolapse, Obstet Gynecol 2008, 111(1):152-7.) The reported failure rates are consistent with those I have seen in my practice. Higher than desired failure rates of native tissue prolapse repairs is a commonly known phenomenon among experienced pelvic surgeons, and before Gynemesh PS and Prolift

were marketed, the need for more durable repairs was widely acknowledged among experienced pelvic surgeons.

Abdominal Sacrocolpopexy

Because of the significant contribution of the apex to anterior vaginal support, the best surgical correction of the anterior and posterior walls may fail unless the apex is adequately supported. Abdominal sacrocolpopexy is an effective treatment for apical prolapse and involves the fixation of mesh to the vaginal apex and to the sacrum. I currently use Gynemesh PS flat mesh in abdominal sacrocolpopexies and have used type I polypropylene mesh for these repairs for more than 20 years. Abdominal sacrocolpopexy may be performed as an open or laparoscopic procedure. Sacrocolpopexy with use of synthetic mesh is superior to using biologic grafts. (Culligan, et al, A randomized controlled trial comparing fascia lata and synthetic mesh for sacral colpopopexy, Obstet Gynecol 2005, 106:29-37.) The use of Gore-Tex grafts has been associated with high rates of intestinal complications, and Marlex has been associated with higher rates of erosion than macroporous, monofilament polypropylene mesh such as Gynemesh PS. (Thompson, et al, Abdominal sacrocolpopexy utilizing Gore-Tex in genital prolapse, J Pelvic Med Surg 2004 Nov/Dec, 10(6):311-7; Nygaard, et al, Abdominal sacrocolpopexy: A comprehensive review, Obstet Gynecol 2004, 104(4):805-23.) ASC is associated with a lower rate of recurrent vault prolapse and dyspareunia than sacrospinous colpopexy. (Maher, et al, Surgical management of pelvic organ prolapse in women: A short version Cochrane review 2008, Neurourol Urodyn 27:3-12.)

Potential complications of abdominal sacrocolpopexy constitute the same set of potential complications of transvaginal mesh kits like Prolift, and to non-mesh native tissue repairs of apical prolapse, and they include but are not limited to vaginal bleeding, vaginal discharge, de novo SUI, detrusor overactivity and urge incontinence, erosion of mesh, erosion of sutures, pain, dyspareunia, bowel obstruction, bowel dysfunction, recurrence of prolapse and reoperation. (Nygaard, et al, Long-term outcomes following abdominal sacrocolpopoexy for pelvic organ prolapse, J Am Med Assoc 2013 May 15, 309(19):2016-24.) These potential complications are commonly known to all experienced pelvic surgeons. Nygaard and colleagues assessed 215 women who had had ASC over a median follow up time of 7 years. They reported anatomic recurrence at 25%, estimated probability of mesh exposure of 10.5% and surgical re-intervention of 16.7%

Use of Grafts to Augment Surgical Repairs and Development of Prolift

Because the traditional suture-based anterior and posterior repairs for pelvic organ prolapse are associated with high rates of recurrence, surgeons have looked to grafts to augment prolapse repairs. (Sung 2008; Maher 2016.) The first description of using a mesh (tantalum) to treat cystocele occurred in 1955, and in 1970 a collagen mesh was first described. Polypropylene mesh was used to augment prolapse repairs beginning in the 1990s. (Lensen 2013; Nicita, A new operation for genitourinary prolapse, J Urol 1998 Sept, 160:74105; Iglesia, et al, The use of mesh in gynecologic surgery, Int Urogynecol J Pelvic Floor Dysfunct 1997, 8:105-15.)

Prolift was developed by a team of surgeons, all of whom were experienced in the use of synthetic mesh to augment prolapse repairs, to develop and standardize a technique for surgical management of urogenital prolapse via the vaginal approach. The team turned to macroporous monofilament type I mesh, Gynemesh PS, which had been cleared by the FDA in 2002 for both abdominal and transvaginal repairs of pelvic organ prolapse, because of the material's proven biocompatibility. The team also developed tools specifically designed for minimally invasive, transvaginal placement of the mesh. Prolift was made available to surgeons in Prolift Anterior, to treat cystocele, Prolift Posterior, to treat rectocele, and Prolift Total, to treat all three compartments. (Fatton et al, Transvaginal repair of genital prolapse: preliminary results of a new tension-free vaginal mesh (Prolift technique)—a case series multicentric study, Int Urogynecol Amblard et al, From the TVM to the Prolift (Gynecare): Evolution of a technique for prosthetic support to treat prolapse via the vaginal route, concerning a retrospective multicentric series of 794 patients (684 TVM/110 Prolift), Pel Perineol 2007, 1:1-9.)

V. Instructions for Use, Professional Education Materials and Patient Brochures

I have reviewed Ethicon's professional education materials including the Prolift Surgical Technique Guide and Surgeon's Resource Monograph, as well as the Prolift and Gynemesh PS IFUs.

These materials warn surgeons of the risks of the devices. The risks of Prolift and Gynemesh PS, as set forth above, constitute a similar set of risks attendant to other surgical prolapse repairs. The IFUs state that users of the devices should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing Gynemesh PS for pelvic reconstruction. The IFUs further state that acceptable surgical practices should be followed for the management of infected or contaminated wounds and that subsequent infection may require additional surgical procedures such as removal of the mesh. Potential adverse reactions that are listed are infection potentiation, inflammation, adhesion formation, fistula formation, erosion and extrusion.

The risks in the Prolift and Gynemesh PS IFUs and in Ethicon's professional education materials are appropriate because they reflect the risks reported in peer-reviewed medical literature as well as the risks observed by pelvic surgeons. The IFUs do not contain, and need not contain, every possible risk of Gynemesh PS or Prolift. These risks and other risks of Gynemesh PS and Prolift, as discussed in this report, are commonly known to experienced pelvic floor surgeons as a result of the surgeons' education and training, professional experience, discussion with peers at medical society conferences, and review of the medical literature. It is routine quality practice for each surgeon to be familiar with risks of a procedure and/or device based on these sources along with review of the IFU and professional education materials. The risks of Gynemesh PS and Prolift have also been publicized in the 2008 and 2011 FDA public health notifications, although they were well known to experienced pelvic surgeons prior to those PHNs.

The Prolift Surgeon's Resource Monograph provides readers with the benefit of the experience of multiple users of Prolift. It discusses surgical technique for implanting Prolift, as well as intra-operative complications including hemorrhage, visceral injury and ureteral obstruction, and such postoperative complications as dyspareunia, vaginal pain, erosions and exposure,

hemorrhage, hematoma, fistula, infection, and urinary retention. The 2007 Prolift professional education slide deck, which was incorporated into training sessions, contains discussion regarding such complications as injury to adjacent organs, bleeding, hemorrhage, cellulitis, abscess, hematoma, contraction, de novo SUI, fistula, mesh exposures, dyspareunia and pain.

I have considered the FDA Device Labeling Guidance #G91-1 "Blue Book Memo," as well as 21 CFR 801.109(c), and Ethicon's Standard Operating Procedure on Labeling provide guidance with regard to what warnings information must be included in medical device labeling. However, it is my opinion that the peer reviewed medical literature provides the best information on adverse events that have been experienced by women.

VI. Evidence from the Scientific Literature

Withagen and colleagues conducted an RCT assessing Prolift Total vs. traditional repair in all compartments in 190 women randomly assigned to mesh-based or non-mesh-based repair. (Withagen et al, Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial, Obstet Gynecol 2011 Feb, 117(2 Pt 1):242-50.) 186 women were assessed at 12 months. At 12 months, anatomic failure was noted in only 9.5% of patients treated with Prolift but in 45.2% of patients treated with non-mesh repairs; this marked difference in failure rates remained highly significant even if lost-to-follow-up patients in the Prolift group were all considered failures and if the lost-to-follow-up patients in the non-mesh group were all considered successes. Four patients in the non-mesh group underwent reoperation prior to 12-month follow up as a result of symptomatic recurrence (3 out of 4 of whom had Prolifts), and no patients in the Prolift group underwent reoperation for symptomatic recurrence. Failure rates were higher in the non-mesh group for both anterior compartment and posterior compartment, whereas no difference was noted in the failure rate of apical repairs between the two groups. Subjective improvement was reported by 81% of patients in the Prolift group and 80% of patients in the non-mesh group. Patients in both groups reported improvement with bulge symptoms and overactive bladder.

Temporary urinary retention was the most common complication in both groups, with voiding returning to normal within 14 days for all patients. The authors noted that their mesh exposure rate was higher than the rate reported by most other authors, and posited several theories to explain why. However, the majority of the exposures were both asymptomatic and conservatively treated, and those that required intervention were fully resolved by that intervention. 14 patients receiving Prolift, or 16.9%, experienced mesh exposure, although 9 of the 14 were asymptomatic and treated with estrogen cream. 5 of the 14 were treated with surgical excision of the exposure in an outpatient setting and exposure in all 5 of those patients resolved. Sexual function was equivalent in both groups. Dyspareunia decreased in both groups compared to baseline, and de novo dyspareunia was equivalent between the mesh (8%) and non-mesh (10%) groups. Reports of de novo SUI also were equivalent between the two treatment groups (9% in the non-mesh group and 10% in the Prolift group).

Svabik and colleagues' trial comparing Prolift Total to native-tissue repair randomized 70 women into the two treatment groups. (Svabik et al, Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy

in patients with levator ani avulsion: a randomized controlled trial, Ultrasound Obstet Gynecol 2014 Apr, 43(4):365-71.) Entry criteria for the study included hysterectomy and at least a two-compartment prolapse and complete unilateral or bilateral levator ani avulsion injury, an injury associated with vaginal childbirth, by which the puborectalis/pubovisceralis muscle becomes detached from its insertion on the inferior pubic ramus, leading over time to enlargement of the levator hiatus. Women with levator avulsion defects are approximately twice as likely to exhibit stage two or higher pelvic organ prolapse (especially cystocele and uterine prolapse), and these patients' risk of recurrence after anterior colporrhaphy is three to four times higher.

The primary outcome for Svabik and colleagues' RCT was anatomical failure based on clinical and ultrasound assessment, and secondary outcomes were evaluation of continence, sexual function and prolapse symptoms based on validated questionnaires. Follow-up was conducted at 3 months and 12 months. At one year follow up, only one patient in the Prolift group (3%) and 22 patients in the non-mesh group (65%) were anatomical failures based on clinical examination (using ultrasound, one patient in the Prolift group and 21 patients in the non-mesh group were assessed to be anatomic failures). Three patients in the non-mesh group were diagnosed with symptomatic recurrence of prolapse at only 3 months follow-up; all were treated with reoperation with Prolift. At 3 months, no patient in the Prolift group was diagnosed with symptomatic recurrence.

Sexual activity was equivalent between the two groups and rates of dyspareunia were low; at one year, two patients in the Prolift group and one in the non-mesh group had dyspareunia.

At 3 months, 3 patients in the Prolift group (8%) had minor mesh exposure. Two of the exposures were resected during the already planned TVT-O procedure and the third exposure was asymptomatic and treated conservatively. There were no additional exposures at one-year follow up. Five (15%) patients in the non-mesh group had vaginal blood spotting due to granulation tissue and all were treated on an outpatient basis. At one year, 13 patients in the Prolift group and 3 patients in the non-mesh group had de novo SUI.

Altman and colleagues' multi-center, parallel-group, randomized controlled trial found that Prolift resulted in significantly higher rate of success than traditional colporrhaphy. (Altman et al, Anterior colporrhaphy versus transvaginal mesh for pelvic organ prolapse, N Engl J Med 2011 May 12, 364(19):1826-36.) Their RCT compared the use of Prolift to anterior colporrhaphy to treat cystocele, the most common type of pelvic organ prolapse. The primary outcome was a composite of the objective stage 0 or 1 prolapse as well as the subjective absence of vaginal bulge symptoms 12 months after surgery. They assessed 389 women randomly assigned to either the Prolift group (200 women) or the colporrhaphy group (189 women).

At 12 months follow-up, 60.8% of the women in the Prolift group achieved the primary outcome, versus only 34.5% of women in the colporrhaphy group. Prolift therefore resulted in significantly higher rates of successful treatment after 1 year.

Complications in the mesh group were low, although higher in the mesh group than in the colporrhaphy group, including rate of bladder perforation (3.5% vs. 0.5%). 3.2% of 186 patients

who had Prolift had repeat surgery to treat mesh exposure. Both treatment groups reported similar rates of sexual satisfaction post operatively.

Halaska and colleagues' multi-center RCT compared Prolift with native tissue anterior and/or posterior repair and sacrospinous fixation to treat vault prolapse. (Halaska et al, A multicenter randomized prospective controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of posthysterectomy vaginal vault prolapse, Am J Obstet Gynecol 2012 Oct, 301.e1-7.) 168 patients were randomized to the two surgical groups and follow-up was conducted at three and 12 months; patients in the Prolift group were noted to be more likely to be engaged in hard, physical work.

The prolapse recurrence rate was significantly higher at 12 months in the non-mesh group than in the group treated with Prolift (39.4% vs. 16.9%, respectively). Recurrence in the non-mesh group occurred most commonly in the anterior compartment (57.1% of recurrences) whereas recurrence in the Prolift group occurred more commonly in the posterior compartment (53.8% of recurrences). Three patients in the non-mesh group and one patient in the Prolift group required reoperation. The authors noted that the difference in recurrence rates between the non-mesh and Prolift groups was significant.

Although the mesh exposure rate was 20.8%, three-quarters of the exposures were asymptomatic, and of the symptomatic exposures, 6 of them (37.5%) resolved with estrogen therapy alone, another 4 resolved with excision under local anesthesia, and 6 were treated with excision under general anesthesia. No significant differences were observed in changes in quality of sexual life between the non-mesh and Prolift groups.

Injury to pelvic organs, postoperative hematomas and infections were infrequent in both groups, and there were no significant differences in rates of de novo SUI or overactive bladder. There was no statistically significant difference in rates of postoperative pelvic pain.

Da Silveira and colleagues' multicenter randomized trial compared outcomes of 184 women with severe pelvic organ prolapse (stage 3 or 4) who were randomly assigned to Prolift or site-specific repair. (da Silveira, Multicenter randomized trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment, Int Urogynecol J 2015 Mar, 26(3):335-43.) At one year, treatment response in the Prolift group was superior to that seen in the non-mesh group in the anterior compartment. There was a significant improvement in the quality of life in both groups, but a greater improvement in quality of life in the Prolift group.

The only difference between the treatment groups with regard to complications was seen with mesh exposure, but 15 of the 18 patients with mesh exposure were treated with topical estrogen cream. Despite the mesh group having a higher rate of complications due to the occurrence of mesh exposures, patient satisfaction was high in the Prolift group. The authors reported a higher rate of exposure than other authors (20%), but they did not routinely treat patients before or after surgery with estrogen cream, included patients in the study who had concomitant hysterectomy and noted that different surgeons had performed the surgeries.

Rates of dyspareunia were not significantly different between the two groups (6.2% in the non-mesh group vs. 3.4% in the Prolift group). Rates of bleeding, infection, difficulty urinating or defecating and recurrence were also not significantly different between the two groups. Pain was reported in more non-mesh-repair patients than Prolift patients (8.6% vs. 2.3%).

Schimpf and colleagues conducted a systematic review of studies of transvaginal prolapse repairs that compared graft or mesh use with either native tissue repair or use of a different graft or mesh, assessing anatomic and symptomatic outcomes, with a minimum of 12 months of follow-up.

In the anterior compartment, Schimpf and colleagues analyzed 20 studies comparing anatomic efficacy and functional outcomes after synthetic nonabsorbable mesh augmentation vs. native tissue repair. Thirteen of the studies were RCTs and seven were cohort studies; all but one study used low-weight, macroporous monofilament polypropylene mesh, and half of the studies used a transvaginal mesh kit (including Prolift) whereas the others used self-tailored mesh (including Gynemesh PS). The authors noted that the quality of the literature had improved substantially over time. The authors concluded that there is high-quality evidence that the use of synthetic nonabsorbable mesh improves anatomic outcomes compared with native tissue anterior colporrhaphy. The authors' meta-analyses of bulge symptoms and Pelvic Organ Prolapse Distress Inventory score significantly favored the use of mesh. Erosion rates across the studies ranged from 1.4% - 19% with most erosions treated in the office. Schimpf and colleagues noted there is also high-quality evidence to suggest no difference for subjective outcomes including quality of life and urinary and sexual function when comparing nonabsorbable synthetic mesh and native tissue repair in the anterior compartment.

The authors noted that data on use of synthetic mesh in repair of isolated posterior vaginal prolapse remain limited. In the posterior compartment, the authors found, the current evidence suggests there is no difference in anatomic and quality of life outcomes when using synthetic absorbable mesh, synthetic nonabsorbable mesh or biologic graft compared with native tissue for transvaginal repair of posterior vaginal prolapse. Data on urinary and sexual function did not show significant improvement with mesh or graft use, and graft exposure and complication rates were low. The authors noted that one prospective cohort study showed that anatomic failure occurred less often with the use of synthetic nonabsorbable mesh compared with native tissue, but the quality of the evidence was low.

Maher and colleagues' 2016 Cochrane review of transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse analyzed 25 RCTs comparing permanent mesh to native tissue repair. (Maher 2016.) Ten of the RCTs used Prolift or transvaginal placement of Gynemesh PS. Most of the other mesh products used in the remaining RCTs were nonabsorbable polypropylene macroporous monofilament type I meshes.

Maher and colleagues' meta-analysis found that when transvaginal permanent mesh was compared to native tissue vaginal repair, the advantages of transvaginal mesh included decreased awareness of prolapse, decreased prolapse on examination and decreased reoperation for prolapse. Maher's analysis noted that transvaginal mesh is also associated with higher rates of repeat surgery for prolapse or SUI or mesh exposure as a composite outcome, and with higher

rates of bladder injury at surgery and de novo SUI. There was no evidence of a difference between the groups in rates of repeat surgery for continence. There was no evidence of a difference between the groups in rates of de novo dyspareunia.

While bladder injury, de novo SUI or mesh exposure were lower for native tissue repair, these adverse outcomes are routinely managed or in the case of de novo SUI can be prophylactically or subsequently managed with a minimally invasive midurethral sling. Maher's meta-analysis concluded that there are advantages to using transvaginal permanent mesh compared to native tissue repair.

Governing Board Committee Opinions and Guideline Statements:

The American College of Obstetrics & Gynecology (ACOG) is the major authoritative board for practice guidelines and quality assurance for Obstetrics & Gynecology. ACOG continues to posit that there is a role for synthetic vaginal mesh in prolapse repairs. The American Urogynecologic Society (AUGS) is the highest academic and educational body for training, policies and guidelines for the specialty of Urogynecology—Female Pelvic Medicine & Reconstructive Surgery. I am a member of both organizations, routinely attend their academic meetings, and maintain my scientific aptitude through their continuing education and publications. These boards establish the treatment guidelines as well as training guidelines for obstetricians, gynecologists and fellowship-trained female pelvic medicine specialists.

In 2011, in a Committee Opinion published jointly between ACOG and AUGS, the relative merits and risks are described for both native tissue repairs and mesh augmented repairs. The position statement was created after the knowledge that the FDA had issued public health notifications related to vaginal mesh in 2008 and 2011. The Committee opinion does not suggest banning the use of vaginal mesh, nor does it state that there is 'no role' for vaginal mesh, but instead provides guidelines for selecting patients for vaginal mesh and consideration of such factors as recurrence of prolapse and medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures. The Opinion further states that, "The approach to the repair of POP should take into account the patient's medical and surgical history, severity of prolapse, and patient preference after education regarding the benefits and risks of the surgical and nonsurgical alternatives." (ACOG Committee Opinion #513, December 2011.)

This is an authoritative position statement by two of the most highly respected administrative organizations related to female pelvic surgery. The message is very clear: there are risks as well as benefits to all procedures, and patient selection and the risks and benefits discussions are the responsibility of the surgeons with their patients. It is the responsibility of the physician to follow guidelines and within the guidelines it is then the honorable responsibility of each physician to educate their patients, to counsel them, and for the physician and patient together to select procedures which have been endorsed by the governing bodies.

In 2013, the American Urogynecologic Society published a Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders. In the position statement, AUGS noted that it is a nonprofit organization of over 1,500 physician and allied health members and represents the

largest professional society representing Female Pelvic Medicine and Reconstructive Surgery specialists who specialize in treating pelvic floor disorders. AUGS, in preparing this position statement, worked with (and continues to work with) both the FDA and the National Institutes of Health (NIH) in reaching their recommendations. This is a coordinated effort of the leading pelvic reconstructive board, the national government agency responsible for product safety, and the most respected national research institute. AUGS stated:

> The American Urogynecologic Society strongly opposes any restrictions by state or local medical organizations, health care systems, or insurance companies which ban currently available surgical options performed by qualified and credentialed surgeons on appropriately informed patients with pelvic floor disorders.

The Position Statement further states that a decision on surgical alternatives should be made by the patient and her surgeon, and that in some circumstances, transvaginal mesh for pelvic organ prolapse may be the most appropriate surgical option. I agree with the Position Statements published by AUGS in coordination with the FDA and the NIH.

The position statement additionally states that "No one approach has proven to be superior in all cases and it is particularly essential that specialists who regularly treat advanced and/or recurrent prolapse are able to maintain a complete set of treatment options in order to provide the most effective and individualized care. A ban on alternative surgical treatment interferes with the patient-physician relationship and withholds FDA acceptable options that the patient and her physician may decide is the best treatment option for her particular clinical situation. A ban on the use of synthetic mesh materials would potentially prohibit many women from accessing the full range of treatment options available." (AUGS Position Statement on Restrictions of Surgical Options for Pelvic Floor Disorders, March 26, 2013)

Perhaps most important in defending a role for type I macroporous polypropylene mesh in vaginal prolapse surgery is the fact that conclusions drawn from multiple reviews, meta–analyses and authoritative position statements each indicate that there is a role for vaginal mesh in appropriately selected and counseled patients.

VII. Complications

The complications seen with Prolift and Gynemesh PS comprise a similar set of complications seen with traditional, native tissue, suture-based repairs of pelvic organ prolapse, and they include acute and/or chronic pain with intercourse; acute and/or chronic pain; vaginal scarring; infection; urinary problems, including frequency, urgency, dysuria, retention or obstruction, incontinence; organ/nerve damage; bleeding; wound complications; inflammation; fistula formation; neuromuscular problems, including in the pelvic floor muscles, lower extremities and/or the abdominal area; one or more surgeries to treat an adverse event; recurrence or failure, including prolapse in an untreated compartment; foreign body response to materials used, whether sutures or grafts; erosion, exposure or extrusion of materials, whether sutures or grafts; and contraction or shrinkage.

I have specifically discussed many of these in my analysis of the medical literature above. With the exception of recurrence/failure rates and mesh exposure, significant differences in complication rates between mesh-augmented and non-mesh prolapse repairs have not been demonstrated. (Maher 2016.) As discussed above, the literature has demonstrated a lower recurrence/failure rate with mesh-augmented repairs in some studies. While mesh exposures are seen in a certain number of cases, the majority of mesh exposures can been treated conservatively or with a minor office-based excision. I discuss exposure and pain in more detail below given the attention these potential complications have been given in the litigation.

Exposure, extrusion and erosion of permanent material other than mesh have been reported with non-mesh-based repairs. Among long-term complications in ULS and SSLF patients, Barber et al reported suture exposure rates at 6 to 24 months postoperatively of 15.4% in ULS patients and 17.2% of SSLF patients. Yazdany and colleagues' review found a 36.1% rate of suture exposure after ULS and Toglia and colleagues' retrospective review found erosion of the suture through vaginal epithelium in 57% of women who had undergone SSLS. (Barber et al, Comparison of 2 transvaginal surgical approaches and perioperative behavioral therapy for apical vaginal prolapse: the OPTIMAL randomized trial, J Am Med Assoc 2014 Mar 12, 311(10):1023-34, incl. Table 8 Adverse Events; Yazdany et al, Suture complications in a teaching institution among patients undergoing uterosacral ligament suspension with permanent braided suture, Int Urogynecol J 2010, 21:813-8; Toglia et al, Suture erosion rates and long-term surgical outcomes in patients undergoing sacrospinous ligament suspension with braided polyester suture, Am J Obstet Gynecol 2008, 198:600.e1-4.)

Exposure is an adverse event that was well documented and reported prior to the launch of Prolift or Gynemesh PS. Abed and colleagues with the Systematic Review Group of the Society of Gynecologic Surgeons performed a systematic review of the adverse events of graft erosion, wound granulation and dyspareunia reported in all vaginal prolapse repair papers using graft materials between 1950 and 2007. They found that graft erosion was documented in 110 studies that included 11,785 women and had a summary incidence of 10.3%. (Abed et al, Incidence and management of graft erosion, wound granulation and dyspareunia following vaginal prolapse repair with graft materials: a systematic review, Int Urogynecol J 2011 Jul, 22(7):789-98.) Maher's Cochrane review meta-analysis found that surgery for mesh exposure was required in 8% of women.

Exposure as a result of implanted synthetic grafts including polypropylene is a phenomenon that has been reported in the literature for many years and has been a complication commonly known to experienced pelvic surgeons. (Stanton, Stress incontinence: Why and how operations work, Urol Clin North Am 1985 May, 12(2):279-84; Iglesia, et al, The use of mesh in gynecologic surgery, Int Urogynecol J 1997, 8:105-115; Dietz, et al, Mechanical properties of urogynecologic implant materials, Int Urogynecol J 2003, 14:239-243; Achtari, et al, Risk factors for mesh erosion after transvaginal surgery using polypropylene (Atrium) or composite polypropylene/polyglactin 910 (Vypro II) mesh, Int Urogynecol J 2005, 16:389-394.)

As discussed above, mesh exposure has been reported in Prolift patients in the peer-reviewed medical literature, including in randomized controlled trials, but the majority of exposures can be treated conservatively, whether expectantly or with topical estrogen cream, or with a minor

excision that can be performed under local anesthesia in the office or in an outpatient setting. A minority of exposures must be treated surgically under general anesthesia. My own experience with patients is consistent with the results reported in the scientific literature.

Other wound healing complications such as infection and inflammatory response and lymphocyte and macrophage reactions with polypropylene mesh have been reported in the medical literature for years and are known to experienced pelvic surgeons. (Choe 2003; Boulanger, et al, Tissue integration and tolerance to meshes used in gynecologic surgery: An experimental study, Eur J Obstet Gynecol Reprod Biol 2006, 125:103-108.) Mesh removal due to defective healing after gynecological surgery with mesh also have been reported for many years. (Wang, et al, A histologic and immunohistochemical analysis of defective vaginal healing after continence taping procedures: A prospective case-controlled pilot study, Am J Obstet Gynecol 2004, 191:1868-1874; Wang, et al, Prospective randomized trial of TVT and TOT as primary treatment for female stress urinary incontinence with or without pelvic organ prolapse in Southeast China, Arch Gynecol Obstet 2010, 281:279-286.)

Pain, including dyspareunia, whether chronic or resolving, has been reported in the medical literature as a complication of almost all surgical prolapse repairs. As discussed above, the literature has demonstrated that reports of pain and dyspareunia after polypropylene mesh are similar to the rates of postoperative pain and dyspareunia reported after non-mesh prolapse repairs. (Dietz et al, Pelvic organ prolapse and sexual function, Int Urogynecol J 2013, 24:1853-7; Lowman et al, Does the Prolift system cause dyspareunia? Am J Obstet Gynecol 2008, 199:707.e1-6; Maher 2016.) It should be noted that with respect to posterior repairs, non-mesh posterior repairs have been assessed to result in postoperative dyspareunia rates ranging from 5 to 46%, which exceeds the de novo dyspareunia rates reported for Prolift. (Karram 2013.)

Lowman and colleagues reported a de novo dyspareunia rate of 16.7% after Prolift, but that 83% of patients with de novo dyspareunia answered "true" on a validated questionnaire to the question, "Overall, the Prolift surgery has improved my quality of life and I would have this surgery done again." (94.7% of all patients answered "true" to this question.) Lowman and colleagues also reported that 50% of patients with pre-existing dyspareunia experienced an improvement in dyspareunia after Prolift. It should also be noted that dyspareunia and sexual function is multi-factorial. (Altman et al, Sexual dysfunction after trocar-guided transvaginal mesh repair of pelvic organ prolapse, Obstet Gynecol 2009 Jan, 113(1):127-133; Gupta et al, The impact of comorbid chronic pain syndromes on sexual activity and dyspareunia after pelvic organ prolapse repair, Urology 2015 Apr, 193(4):e400; Sentilhes et al, Sexual function in women before and after transvaginal mesh repair for pelvic organ prolapse, Int Urogynecol J 2008, 19:763-772.)

The risk of chronic or long-term pain after vaginal surgeries including prolapse repairs, both with and without mesh has long been reported in the literature and is known to experienced pelvic surgeons. (Francis, Jeffcoate, Dyspareunia following vaginal operations, J Obstet Gynaecol Br Common 1961, 1-10; Stanton 1985; Galloway 1987.) Pain other than dyspareunia, both short-term and chronic, has been reported with non-mesh repairs. Barber reported that 12.4% of SSLF patients and ULS patients experienced neurologic pain that required intervention, and 4.3% of SSLF patients experienced persistent pain beyond the postoperative period and that his results

confirmed findings from pervious case series suggesting that SLLF may cause acute neurologic pain, particularly buttock pain that may be the result of gluteal nerve entrapment. (Barber 2014.)

In my experience, in properly selected patients, vaginal mesh is an additional excellent option among a collection of surgical options I may offer my patients. It is not selected for everyone, but it plays an important role for me. Unfortunately, I find that currently many patients choose more invasive options due to media-driven fears of vaginal mesh when in my honest and educated professional opinion, the vaginal mesh may have been the best choice. For every single patient and every single condition I treat, there are multiple options. It is my job as a surgeon to present the options and my recommendations as clearly and objectively as possible, and together, the patient and I make choices. This is a doctor – patient relationship in which we discuss use of procedures and FDA-cleared devices. This appropriate counseling and decision-making process for vaginal mesh is endorsed by the most authoritative societies that govern prolapse repair education, review and quality.

VIII. Response to Plaintiffs' Themes

Biocompatibility of Gynemesh PS

The plaintiffs in this litigation claim that Gynemesh PS, the mesh in Prolift, is "heavyweight" mesh and that the pore size of the mesh is too small. However, Gynemesh PS is macroporous, monofilament type I mesh, which the scientific literature has demonstrated is inert, resists infection and fistula, has rapid fibrinous fixation, becomes completely incorporated into the host tissue, and in case of infection does not need to be removed. Gynemesh PS has a pore size of 2,400 microns. Macroporous monofilament polypropylene mesh with a pore size that is larger than 75 microns does not promote or harbor infection, and mesh with pore size larger than 100 microns produces complete infiltration of the host tissue into the entire thickness of the mesh in about one month. (Amid 1997; Dietz 2003; Jones et al, Tensile properties of commonly used prolapse meshes, Int Urogynecol J 2009, 20:847-53.)

Although the plaintiffs in this litigation claim that implantation of Gynemesh PS results in chronic inflammation, this statement misstates the phenomenon that occurs, and that is well understood. As described by Elmer et al., a transient acute inflammatory response, which is necessary for healing and tissue incorporation, is then followed by a mild but persistent foreign body response to polypropylene meshes. (Elmer C, et al, Histological Inflammatory Response to Transvaginal Polypropylene Mesh for Pelvic Reconstructive Surgery, J Urol 2009, 181(3) 1189–1195.)

Cytotoxicity, Degradation and Particle Shedding

The plaintiffs in this litigation claim that the mesh in Prolift is cytotoxic and degrades. There is no peer-reviewed scientific literature that proves their claims, and I have never seen evidence in my practice that patients are harmed by Gynemesh PS being cytotoxic or degrading. In a 2010 article, Clave and colleagues analyzed 100 polypropylene and polyethylene terephthalate implants explanted from patients with complications and observed what appeared to be microscopic cracking and degradation of the samples. These observations led the authors to

question whether polypropylene mesh is truly inert. The authors acknowledged that their study did not provide the opportunity to analyze implants from non-pathological situations; that their sample size was small; that they had not performed a full chemical analysis of every sample; and that they were unable to explain their observations. (Clave, et al, Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants, Int Urogynecol J (2010) 21:261-270.) Thames and colleagues, however, subsequently published the results of a study they performed of explanted Prolene meshes that had been cleaned, from which they concluded that Prolene mesh did not degrade in vivo, that properly formulated polypropylene was stable in vivo, and that the cracked layer identified by other researches was instead an adsorbed protein-formaldehyde coating that resulted from the formalin-protein-fixation process, which occurs immediately upon placing an explant in formalin. (Ong, et al, The myth: in vivo degradation of polypropylene meshes, Int Urogyn J 2016, 27:s37-8; Thames, et al, The myth: in vivo degradation of polypropylene meshes, Int Urogynecol J, 2017 Feb, 28(2):285-97.) Thames and colleagues' findings are consistent with the large body of peer-reviewed medical literature, as well as what I have seen in my practice. No peer-reviewed scientific literature has demonstrated that patients have been harmed by degradation of Gynemesh PS. Other microscopic analyses of macroporous monofilament polypropylene mesh that were removed for reasons other than an infection process are consistent with Thames's findings, and the investigators there concluded that no degradation of polypropylene mesh had occurred. (Fletcher SG and Lemack GE: Re: Histologic comparison of pubovaginal sling graft materials: a comparative study. Urology 2008; 72: 721; Woodruff AJ, Cole EE, Dmochowski RR et al: Histologic comparison of pubovaginal sling graft materials: a comparative study. Urology 2008; 72: 85). The FDA has specifically recognized that the biocompatibility of Prolene has been established [53 Fed. Reg. 23856 (June 24, 1988)]. There is no meta-analysis of biomechanics and alleged degradation or cytotoxicity of synthetic meshes, however, the above citations and the FDA's recognition of the biocompatibility of Prolene provide strong evidence of the biocompatibility of these meshes.

Infection, Bacterial Slime and Biofilm

The plaintiffs claim that the mesh in Prolift, Gynemesh PS, is prone to infection and promotes bacterial slime and biofilm that harms patients. There is no peer-reviewed scientific literature that supports their claims. Macroporous monofilament polypropylene mesh is a Type I mesh with pore sizes larger than 75 microns, and therefore is the most favorable mesh type as it relates to infection risk (Amid 1997.) Infection of the mesh in Prolift is rare, despite the fact that the vagina is a clean-contaminated environment. Bacteria in the human body are attacked by leukocytes and macrophages and eliminated. (Papadimitriou, Petros: Histological studies of monofilament and multifilament polypropylene mesh implants demonstrate equivalent penetration of macrophages between fibrils, Hernia 2005, 9:75). Infection is a risk of any surgery, however, and the IFU warns that acceptable surgical practice be followed as well as for the management of contaminated or infected wounds, that the mesh may potentiate an existing infection and that infection may require removal of the mesh. As noted above, the FDA has specifically recognized that the biocompatibility of Prolene has been established [53 Fed. Reg. 23856 (June 24, 1988)]

Shrinkage and Contraction

The plaintiffs claim that the mesh in Prolift shrinks and contracts, harming patients. The literature on this is varied. However, shrinkage/contraction is a phenomenon that was known and reported in the scientific literature before Gynemesh PS and Prolift were marketed (Amid 1997; Deprest, et al, Synthetic and biodegradable prostheses in pelvic floor surgery, International Congress Series 1279, 2005, 387-397), and it is associated with non-mesh surgeries as well, in that scar tissue shrinks and contracts. The Prolift IFU includes scarring resulting in implant contraction. The Prolift Surgeon's Resource Monograph notes that "The collagen-dominant layer that invests the mesh will contract over time and cause an estimated 10-20% contraction. This is why it is important to avoid excessive mesh trimming intraoperatively."

Cancer

The plaintiffs claim that the mesh in Prolift causes cancer. However, to my knowledge, no reports of malignancy have been reported in humans in association with polypropylene grafts or suture, even with polypropylene mesh slings having been used since the late 1990s and implanted in millions of patients worldwide. Type I polypropylene meshes having been used for even longer periods of time in abdominal hernia repairs. No reliable scientific data have shown an association between cancer and the use of polypropylene mesh or suture.

Vypro, PVDF and Ultrapro

The plaintiffs claim that other meshes, such as Vypro, PVDF and Ultrapro are safer than or superior to the mesh in Prolift. With regard to PVDF, I am not aware of this material being available in the U.S. for gynecological applications. (Okulu E, et al, Use of three types of synthetic mesh material in sling surgery: a prospective randomized clinical trial evaluating effectiveness and complications, Scan J Urol 2013: 47: 217-224; Najjari, et al, Visualization of polypropylene and polyvinylidene fluoride slings in perineal ultrasound and correlation with clinical outcome, BioMed Res Int, 2014, doi:10.1155/2014/181035; Najjari, et al, Comparing different types of suburethral slings using perineal ultrasound, ICS Abs 401, 2012; Goretzlehner, et al, PVDF as an implant material in urogynaecology, Biomaterialien 2007, 8(S1):28-9.)

Vypro is a blend of absorbable (polyglactin 910) and non-absorbable polypropylene. Ultrapro, also, is a blend of polypropylene and absorbable poliglecaprone. Although Ultrapro and Vypro have been studied in some trials, neither has been demonstrated to be safer or more efficacious than Gynemesh PS in the scientific literature. (Achtari et al, Risk factors for mesh erosion after transvaginal surgery using polypropylene (Atrium) or composite polypropylene/polyglactin 910 (Vypro II) mesh, Int Urogynecol J 2005, 16:389-394; Gupta et al, Anterior vaginal prolapse repair: A randomised trial of traditional anterior colporrhaphy and self-tailored mesh repair, South African J Obstet Gynecol 2014, 20(3):47-50; Denis et al, Pelvic organ prolapse treatment by the vaginal route using a Vypro composite mesh: preliminary results about 106 cases, ICS Abstracts 620.)

Ultrapro has shown rates of mesh exposure and dyspareunia that are comparable to Gynemesh PS, and this material has not been demonstrated to be more efficacious. (Lensen et al,

Comparison of two trocar-guided trans-vaginal mesh systems for repair of pelvic organ prolapse: a retrospective cohort study, Int Urogynecol J 2013, 24 (10), 1723-1731; Milani et al, Medium-term clinical outcomes following trocar-guided mesh repair of vaginal prolapse using partially absorbable mesh, Int Urogynecol J 2012, 23 (Suppl): S43-S244; Bhatia et al, A comparison of sexual function outcomes 1 year after undergoing a transvaginal mesh procedure using polypropylene mesh vs. hybrid polypropylene/poliglecaprone mesh, Female Pelvic Med Reconstr Surg 2012 Mar/Apr, 18 (2 Pt 1): S20; Quenemer J et al, Rate of re-interventions after transvaginal pelvic organ prolapse repair using partially absorbable mesh: 20 months medium follow-up outcomes, Eur J Obstet Gynecol Reprod Biol 2014, 175:194-8.)